

### **Remarks**

Claims 1-107 were pending. Claims 53-76 and 79-107 are withdrawn. Claims 1, 4-6, 8, 9, 14-16, 29, 31, 32, 34-37, 39, 48, 49 and 77 are amended. Claim 3 is canceled without prejudice or disclaimer for being redundant with amended claim 1. Applicants submit that no new matter is added by the amendment.

### **Amendment to the Specification**

Specification has been amended to remove typographical and grammatical errors, as well as to include trademark symbols where necessary, as required to by the Examiner. The paragraph numbers used in this response refer to the published Application 2007/0183970.

### **Amendment to the Claims**

Claim 1 has been amended to include the CDR sequences of the antibody MN-3. These sequences were previously recited in dependent claim 3. Claim 3 has now been canceled. Accordingly, claims 4, 8, 77 which depended from claim 3 are amended to indicate the correct dependency from amended claim 1.

Claim 4 is further amended to clarify the claimed subject matter by inserting the word "humanized" in the preamble and deleting the phrase "is a humanized antibody or fragment." Similarly claims 5, 6, 8, 9, 14-16, 29, 31, 32, 34-37, 39, 48, 49 and 77 are amended to clarify the claimed subject matter by inserting in the preamble words "chimeric" or "humanized" or "chimeric or humanized" as appropriate.

Claim 6 has been amended to correct dependency and to provide proper antecedent basis.

### **Claim Rejections - § 112 vagueness and indefiniteness**

*MN-3*

Claims 3-6, 8 and 9 were rejected for indefiniteness, since there was insufficient antecedent basis for the limitation MN-3. As noted in the Action, this was due to a typographical error in Claim 1. Claim 1 has been amended to correct the error so that it recites MN-3 and provides proper antecedent basis for claims 4-6, 8 and 9. Claim 3 has been canceled.

*Amendment of claim 1*

Claims 1, 3-6, 8, 9, 14-16, 29, 31, 32, 34-37, 39, 48-52, 77 and 78 were rejected for being vague and indefinite. The Action stated that the rejection can be obviated by amending the claims to specifically and uniquely identify MN-3 by SEQ ID NO. While Applicants traverse this rejection, in the interest of advancing prosecution Applicants have amended claim 1 by including the CDR sequences that uniquely identify MN-3. These sequences were previously recited in Claim 3 which has now been canceled.

*Chimeric*

Claims 3-6, 8, 9, 14-16, 29, 31, 32, 34-37, 39, 48-52, 77 and 78 were rejected for being vague and indefinite in the recitation of “chimeric” in claim 1. The Action states that “it is not clear from the claims or the applicants’ definition of chimeric in the specification (paragraph 105) whether the framework regions of the claimed antibody are human or rodent residues.”

Applicants respectfully traverse. Paragraph [0021] clearly defines chimeric MN-3 as a chimeric MN3 monoclonal antibody or fragment thereof comprising the complementarity-determining regions (CDRs) of a murine MN3 MAb and the framework (FR) regions of the light and heavy chain *variable regions* of a *murine* MAb and the light and heavy chain *constant regions* of a *human* antibody. Paragraph [0112] defines a humanized antibody as a recombinant protein in which the CDRs from an antibody from one species; e.g., a rodent antibody, is

transferred from the heavy and light variable chains of the rodent antibody into human heavy and light variable domains and the constant domains of the antibody molecule is derived from those of a human antibody. Thus, a chimeric MN-3 antibody contains FR sequences from the variable regions of a murine antibody and constant regions of a human antibody, whereas a humanized antibody contains FR sequences from variable and constant regions of a human antibody only.

Claim 1 claims a MN-3 antibody or fragment (either chimeric or humanized) that comprises the claimed murine CDR sequences. As per the definition given in [0021], the chimeric antibody would comprise the FR sequences of the light and heavy chain variable regions of a murine antibody and the light and heavy chain constant regions of a human antibody. Claim 4 claims only the humanized antibody or fragment that comprises the FR sequences of the light and heavy chain variable regions of a human antibody and at least one light and heavy chain constant regions of a human antibody. To avoid any confusion as to the claimed subject matter, applicants have amended claims 4, 8 and 9 by inserting the words chimeric or humanized in the preamble. Similarly claims 5, 6, 14-16, 29, 31, 32, 34-37, 39, 48, 49 and 77 are also amended to clarify the claimed subject matter by inserting in the preamble words "chimeric" or "humanized" or "chimeric or humanized" as appropriate.

Therefore, Applicants submit that the subject matter of claim 1 and dependent claims 3-6, 8, 9, 14-16, 29, 31, 32, 34-37, 39, 48-52, 77 and 78 is now clear and request that the vagueness rejections be withdrawn.

#### **Claim Rejections - § 102 anticipation**

Claims 1, 3-6, 8, 9, 14-16, 29, 31, 34-37, 39 and 48-52 were rejected under 102(a) as being anticipated by Goldenberg (U.S. 6,759,045), Hansen 1 (Cancer, 1993, Vol. 71:3478-85) and Becker (Journal of Nuclear Medicine, 1994, Vol. 35:1436-43).

Applicants respectfully submit that despite the mention of the MN-3 MAb in Goldenberg, Hansen and Becker, none of the references disclose the sequence of the MN-3 antibody. Furthermore, the hybridoma producing this antibody was not publicly available at the time of the effective filing date of this application. [See attached declaration of Dr. Hans J. Hansen.] Therefore, one of ordinary skill in the art could not have obtained the CDR sequences of the MN-3 antibody. Since none of these references disclose the element of “comprising the MN-3 light chain CDR sequences CDR1 (RSSQSIVHSNGNTYLE, SEQ ID NO:1), CDR2 (KVSNRFS, SEQ ID NO:2) and CDR3 (FQGSHVPPT, SEQ ID NO:3) and the MN-3 heavy chain CDR sequences CDR1 (NYGMN, SEQ ID NO:4), CDR2 (WINTYTGEPTYADDFKG, SEQ ID NO:5) and CDR3 (KGWMDFNSSLDY, SEQ ID NO:6)” of the amended claim 1, Applicants respectfully submit that the claimed subject matter is not anticipated by these references.

**Claim Rejections - § 103 (a) obviousness**

Claims 1, 3-6, 8, 9, 14-16, 29, 31, 34-37, 39, 48-52, 77 and 78 were rejected under 103(a) as being obvious over Goldenberg as evidenced by Hansen 1 and Becker in view of Hansen 2 (US PG PUB 2002/0006379). Claims 1, 3-6, 8, 9, 14-16, 29, 31, 34-37, 39 and 48-52 were also rejected under 103(a) as being obvious over Goldenberg as evidenced by Hansen 1 and Becker in view of Orlandi (PNAS, 86:3833-37, 1989), Cabilly (U.S. 4816567), Boss (U.S. 4816397), Robinson (U.S. 5618920), Ward (Nature 341:544-46, 1989) and Huston (U.S. 5258498). The Action states that the Goldenberg reference constitutes prior art only under 102(e) and the rejections can be overcome by showing that the reference is disqualified under 35 USC 103(c) as prior art under 103(a). [See Action at pages 11 and 16.]

*Statement of common ownership*

Applicants' representative respectfully asserts that the subject matter claimed in the instant application and the subject matter claimed in U.S. Patent No. 6,759,045 (Goldenberg *et al.*) were commonly owned by, or subject to an obligation of assignment to, the same person (Immunomedics, Inc.) at the time the instant invention was made.

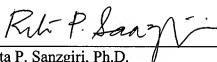
Therefore, the Goldenberg reference is disqualified as prior art and accordingly Applicants request that both obviousness rejections be withdrawn.

### **Conclusion**

Applicants respectfully submit that the amended claims are now in condition for allowance and request withdrawal of all rejections.

Respectfully submitted,

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